CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 22.1
TITLE: PHARMACY

AUTHORITY: 38 CFR 17.270(a) and 17.272(a)

RELATED AUTHORITY: 32 CFR 199.2(b), (b)(2)(v), (b)(3)(iii), (b)(5)(v), (d)(3)(vi), and (e)(11)(i)

I. EFFECTIVE DATE

A. Labeled use: the effective date of FDA (Food and Drug Administration) approval for the specific labeled indication/use.

B. Off-labeled use: the effective date of the FDA approval for the latest specific labeled indication/use; or if medical literature supports prior safety and efficacy, the first effective date of FDA approval of the drug for general use in humans may be used.

C. Orphan drugs: the effective date of the FDA's marketing approval for the proposed use. Orphaned drugs are defined as a drug or biological product that is used for the diagnosis, treatment, or prevention of a rare disease or condition. A rare disease is defined as any disease or condition that affects less than 200,000 persons in the United States.

II. POLICY

A. Drugs and medicines, including "unlabeled or off-label indications," administered by a physician or obtained by prescription, are covered as follows:

1. Labeled Indications.

a. The drug or medicine is approved by the FDA.

b. The drug or medicine is prescribed or ordered by a physician or other authorized professional provider who has determined the drug as medically necessary for the treatment of the condition.

c. The drug or medicine prescribed is dispensed in accordance with all applicable state laws and licensing requirements.

2. Off-label Use. Approval for “unlabeled or off-label use” requires medical review for medical necessity. Drugs or medicines are covered for off-label use when there is reliable evidence, such as clinical studies, demonstrating such usage is safe and effective and generally accepted standard of practice in the general medical community. The following hierarchy of reliable evidence is used:

a. Well-controlled clinical studies, published in referenced medical literature.

b. Published in formal technology assessments, such as Hayes Inc..

c. Published in national medical policy organizations, such as the AHA (American Heart Association), and AMA (American Medical Association).

d. Published in reports of national expert opinion organizations, such as the ACS (American Cancer Society).

3. If the "off-label or unlabeled" use of the drug is questionable regarding the safety, effectiveness, or whether it is a nationally accepted standard in the medical community, VA (Veteran’s Affairs) coverage of the drug will be denied.

4. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be covered if FDA approved. A drug that is approved for testing in humans is not covered. Information concerning FDA approved drugs may be obtained by calling 1-888-INFOFDA or by visiting the FDA web site at www.fda.gov/cder/da/ddpa.htm.

5. Orphan drugs. Pharmaceutical agents with FDA “orphan drug” designation and marketing approval are covered when used in the treatment of a rare disease or condition.

6. Drugs which previously required a prescription but which are now deemed safe by the FDA for use without a doctor's prescription and are available over-the-counter, are not reimbursable.

B. The prescription and the number of authorized refills will not result in more than a 12-month supply.

1. No more than a 90-day supply of medication will be filled at one time.

2. Controlled substances (Schedule III, IV, and V) will be covered for a 30-day supply with a maximum of 5-refills in a 6-month period. The exception to this is for controlled substances used for seizure control. These prescriptions may be dispensed in up to 90-day quantities with one refill.

3. Schedule II controlled substances prescriptions will be covered for a 30-day nonrefillable supply and will require a new prescription for each 30-day period. The exception to this is for drugs used for treating ADD (Attention Deficit Disorder), which can be dispensed in up to 90-day quantities.

4. No prescription may be refilled until 75-percent of the prior prescription is expended unless the patient or doctor provides a suitable explanation as to why the early fill is necessary.

III. POLICY CONSIDERATIONS

A. CHAMPVA provides a pharmacy benefit that includes a mail order prescription service. For more information regarding this benefit see Chapter 1, Section 4.2, *MbM (Meds By Mail)*.

B. Insulin and related supplies are covered for diabetic patients regardless of whether or not a prescription is required under state law. For information regarding insulin pumps see Chapter 2, Section 17.15, *External Infusion Pump*.

C. Beneficiaries who reside in the United States and order their prescriptions from foreign countries must comply with the same criteria as outlined within this policy. Reimbursement will be made in accordance with the procedures outlined within Chapter 3, Section 5.11, *Pharmacy Reimbursement.*

D. CHAMPVA shall accept store/pharmacy sales receipts, that is, a cash register receipt with a date and dollar amount that corresponds with the pharmacy's invoice/billing statement. The following minimum data requirements apply:

1. The name of the patient

2. The name of pharmacy, address and phone number

3. The name of prescribing physician

4. The NDC (National Drug Code), name, strength and quantity of each drug

5. An itemized charge for each drug

6. The date the prescription was filled

E. Prescriptions will be reimbursed separately based on the date of service; "Your Pharmacy" will be used on the EOB (Explanation of Benefits) for nonassigned prescription claims. A “profile statement” (drug purchase history) of dispensed medications may be submitted for claim processing purposes when it includes provider identification information.

F. Prescriptions for controlled substances written by providers who do not have individually assigned DEA (Drug Enforcement Agency) numbers shall not be accepted.

G. Prepaid prescription plan. Where the beneficiary pays only a "flat fee" no matter what the actual cost of the drug, CHAMPVA shall cover the fee and not develop for the actual cost of the drug, since the beneficiary is only liable for the "fee."

H. Treatment of organic male impotence will be covered only after thorough evaluation has been documented by the physician.

1. Prescribed medications, such as Viagra, Levitra, and Cialis by physicians treating male patients diagnosed with organic impotence, are covered when the physician has considered the medication as the most optimal regime for the patient.

2. Dispensing of prescribed medications must adhere to established clinical guidelines.

3. “Lost”, “stolen”, or “destroyed” tablets will not be replaced.

I. Viagra is covered when prescribed by a physician for the treatment of pulmonary hypertension in adult or pediatric patients.

IV. EXCEPTIONS

A. Medical care related to the use of Group-C designated drugs is covered only when the care would have been provided with nationally accepted standard of practice in the medical community.

B. Drugs and medications for gastric bypass, gastric stapling, or gastroplasty procedures in connection with morbid obesity when determined to be medically necessary.

C. Vitamins or other nutritional supplementals are covered when documentation indicates the use of the vitamin is an accepted standard of practice for the specific treatment of a covered medical condition.

D. Medical care related to the use of treatment of IND’s (Investigational New Drugs) are covered when the patient’s medical condition warrants their administration and the care is provided in accordance with generally accepted standards of medical practice.

V. EXCLUSIONS

A. Drugs and medicines that are not approved for marketing by the FDA.

B. Investigational drugs with FDA "Group-C" designations has reproducible efficacy in one or more specific tumor types. Such a drug has altered or is likely to alter the pattern of treatment of the disease and can be safely administered by properly trained physicians without specialized supportive care facilities. CHAMPVA cannot cost share use of Group-C designated drugs because authorization for Group-C distribution for a specific indication is not equivalent to formal FDA approval for that indication.

C. Drugs and medicines prescribed or provided by a member of the beneficiary's immediate family, or a person living in the beneficiary or sponsor's household. [38 CFR 17.272(a)(15)]

D. Drugs and medicines prescribed in connection with cosmetic surgery that is performed to primarily improve physical appearance or for psychological purposes to restore form without correcting or materially improving a bodily function. [38 CFR 17.272(a)(19)]

E. Drugs and medicines prescribed for nonsurgical treatment of obesity, dietary control, or weight reduction. [38 CFR 17.272(a)(22)]

F. Nonprescription contraceptives. [38 CFR 17.272(a)(29)]

G. Vitamins or other nutritional supplements, including those related to prenatal care for a home patient whose condition permits oral feeding. [38 CFR 17.272(a)(51)]

H. Smoking cessation drugs and supplies, such as nicotine patches. [38 CFR 17.272(a)(57)]

I. Prescriptions to be utilized in drug maintenance programs where one addictive drug is substituted for another, such as methadone substituted for heroin. [38 CFR 17.272(a)(72)]

J. All drugs, including compounded preparations not requiring a prescription (over-the-counter purchases) except for insulin and related diabetic testing supplies and syringes. [38 CFR 17.272(a)(80)]

K. Prescriptions written after the beneficiary's eligibility period has expired.

L. The following list of drugs are not covered for “unlabeled or off-label use: The list is not all-inclusive.

1. Adrenal cortex extract injections

2. Autotogenous vaccines

3. Heparin therapy in the treatment of pregnant patients who have SLE (Systemic Lupus Erythematosus) or who have LA (Lupus Anticoagulant).

4. High dose calcitriol and/or interferon gamma in the treatment of malignant osteopetrosis.

5. HCG (Human Chorionic Gonadotropin) or any other drug administered for purposes of weight control.

6. Interferon.

a. Fa-2b for treatment of bladder cancer.

b. Interferon gamma for the treatment of scleroderma.

c. Interferon Gamma-1b (Actimmune®) for the treatment of idiopathic pulmonary fibrosis.

7. IVIG (Intravenous Immune Globulin) (Venoglobulin®) in the treatment of multiple sclerosis.

8. Intravenous injections of gamma globulin for pregnancy rejection and polycystic ovarian disease.

9. Isotretinoin (Accutane®) as a single-agent treatment or for maintenance of remission of squamous cells carcinoma of the skin.

10. Laetrile (amygdalin, sarcarcinase, vitamin B-17) and all other drugs characterized as a "nitriloside" are not recognized to be safe and effective for any therapeutic use.

11. Methotrexate for systemic lupus erythematosus.

12. Mitomycin-C (Mutamycin®) when used in trabeculectomy (glaucoma filtering surgery).

13. Navelbine® for refractory platinum-resistant epithelial ovarian cancer.

14. Orphan drugs without marketing approval but which are made available on a compassionate use basis.

15. Paclitaxel (Taxol®) for the treatment of malignant melanoma, and adenocarinoma of the colon.

16. Pamidronate (Aredia®) for the treatment of osteoporosis.

17. Placebo injections and drugs. [38 CFR 17.272(a)(14)]

18. Transdermal nicotine patch for the treatment of ulcerative colitis.

19. Treatment INDs not approved by the FDA for commercial marketing or general uses.

END OF POLICY